REMARKS

Favorable reconsideration of the subject application is respectfully requested in view of the amendments above and the comments below.

Claims 1-30 are pending in the present application. Claims 11, 13, 14, 16, 19, 20 and 23 are canceled without prejudice or disclaimer. Claims 2, 3, 5, 7-9, 15, 17, 21, 24-26, 28 and 29 have been amended. Accordingly, claims 1-10 and 12, 15, 17, 18, 21, 22 and 24-30 are presented for examination on the merits.

Claims 2, 3, 5, 7 and 17 have been amended to delete the language "including mammalian homologs or analogs thereof, since such language is superfluous. Claim 9 has been amended to add a screening step. Claims 15, 24-26, 28 and 29 have limited to a *tol* gene or analog or homolog thereof as the secondary target site. The amendment to claim 21 is clerical in nature. All of the amendments are fully supported by the specification.

Rejection of Claims 2, 3, 5-12, 16 and 17 Under 35 U.S.C. § 112, First Paragraph

Claims 2, 3, 5-12, 16 and 17 stand rejected under 35 U.S.C. § 112, first paragraph, as allegedly being indefinite. Claims 11 and 16 have been canceled, thereby rendering the rejection of these claims moot. As to the remaining claims, the Examiner made a finding that it is unclear what is encompassed by the terms "homolog" and "analog." Applicants respectfully disagree with the Examiner's conclusion.

The specification provides at pages 5-6 a definition of the terms "analog" and "homolog" which fall within the art accepted meanings of these terms, *i.e.*, similar in function, but differing

in origin or structure (analog) or similar to some extent in structure but not necessarily in function (homolog).

Moreover, the specification provides numerous examples of various homologs and analogs of *tol* genes, and specifically provides examples thereof at page 22-23. In particular, Example 2 teaches how to identify human homologs of yeast *tol* genes. Moreover, at the time of filing the subject application, *tol1*, *tol2* and *tol3* genes had been isolated in yeast and well characterized. As such, the skilled practitioner is aware of the basic structure and other relevant information necessary for the manipulation of these genes and isolation of homologs and analogs thereof.

Thus, the language of claims 2, 3, 5-10, 12 and 17 meets the requirements of 35 U.S.C. § 112, first paragraph. Accordingly, the rejection of these claims should be withdrawn.

Rejection of Claims 2, 3, 6 and 9-30 Under 35 U.S.C. § 112, First Paragraph

Claims 2, 3, 6 and 9-30 stand rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to meet the written description requirement. Claims 11, 13, 14, 16, 19, 20 and 23 have been canceled, thereby rendering the rejection as to these claims moot.

As to the remaining claims, the Examiner asserts that all of the rejected claims depend on identification of a secondary target site, such as a *tol* gene. The Examiner also asserts that without physical description of the secondary target site, the skilled practitioner would not believe that the applicant was in possession of the claimed invention at the time of filing. The Examiner concludes, therefore, that all of the claims are "reach-through" claims which have no

foundation in subject matter already attained by the inventors. Applicants respectfully disagree with the Examiner.

The present invention is based on the discovery that cells that overexpress telomerase activity can be used to generate secondary target sites that affect cell viability or regulate cell cycling. Applicants have discovered a means of ascertaining the genes involved in the telomerase pathway and have manipulated mutant cells to provide information concerning genes that affect telomerase activity. In particular, applicants have found that cells that overexpress telomerase activity can be used to generate mutants in genes other than the gene causing the overexpression (secondary target sites). Applicants have used the methods and cells disclosed in the specification to generate screening methods for drugs that may be useful for controlling undesired cell growth (tumor cells).

Pending claims 1-10 and 12 are directed to a method for identifying genes or gene products that play a role in cell cycling. According to claim 1, the method requires the use of cells that overexpress telomerase activity, and the specification provides examples of such cells. Claim 1 also requires that these cells are mutagenized and that cells harboring at least one mutation affects their viability when telomerase activity is overexpressed. It is known in the art and the specification teaches that there are numerous genes involved in the telomerase pathway. The specification teaches that these genes, many examples of which are provided throughout the specification and many of which are specifically set forth in the claims, can be used as secondary target sites in the method of the invention. For that matter, claim 6 provides several examples of human homologs of the yeast *tol* genes that are used in the claimed methods. Thus, the specification teaches how to carry out the methods of claims 1-10 and 12.

Pending claims 15, 17 and 18 are directed to method of inhibiting the growth of tumor cells, which are known to have enhanced telomerase activity. According to the specification, the cell model used in pending claims 1-10 and 12 is used to screen candidate drugs that affect the cell cycle. Those candidate drugs are used in the process of pending claims 15, 17 and 18 to inhibit the growth of tumor cells.

Claim 21 is directed to a recombinant cell comprising a primary gene that results in the overexpression of telomerase activity and which contains a mutated secondary site that affects the expression of the primary gene. Such cells are disclosed in detail in the specification, and numerous examples of the primary gene and secondary site are provided. Hence, the specification provides written description of the invention of claim 21.

Claim 22 is directed to a method for screening for drugs that affect the cell cycle by using the cells described in the specification. The specification provides sufficient written description of the cells, the mutations that employed, and the screening process.

Claims 24 and 27 are directed to a method for inhibiting the growth of a tumor cell that has enhanced telomerase activity. As amended, the claim requires administration of a drug that interacts with the *tol* gene or its product. Claims 25-27 and 29 are directed to pharmaceutical compositions that are selected to interact with the *tol* gene or its product. The specification and the prior art provide ample written description of the *tol* gene, and the specification teaches how to manipulate the gene so as to generate drugs that interact therewith.

As such, the specification provides sufficient written description of the claimed invention. Accordingly, the rejection of claims 2, 3, 6, 9, 10, 12, 15, 17, 18, 21, 22 and 24-30 under 35 U.S.C. § 112, first paragraph, is respectfully traversed.

Rejection of Claims 1-12 Under 35 U.S.C. § 112, First Paragraph

Claims 1-12 stand rejected under 35 U.S.C. § 112, first paragraph. Claim 11 has been canceled, thereby rendering the rejection as to this claim moot. As for the remaining claims, the Examiner alleges that the specification does not provide an enabling disclosure to support claims to a method for identifying secondary target sites that encode a lethal mutation in cells harboring a primary gene that results in overexpression of telomerase activity. Applicants respectfully disagree with the Examiner's conclusion.

The present invention teaches the generation of a model cell line that was used to generate mutations in a number of different secondary genes that are involved in the telomerase pathway. The specification teaches that such secondary genes include the human *CHL1* gene, the *ercc2* gene, mouse helicase, and the human type II keratin subunit gene. The specification also provides numerous examples of primary target genes that may be used. These methods have been successfully used to generate secondary target sites. Thus, the specification teaches all that is necessary to enable the skilled practitioner to make and use the claimed invention.

Accordingly, the rejection of claims 1-10 and 12 under 35 U.S.C. § 112, first paragraph, is respectfully traversed.

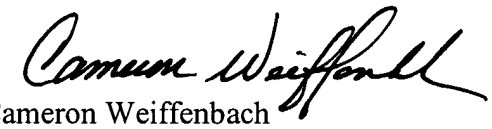
On August 6, 2003, Applicant filed a Revocation of Power of Attorney and Appointment and Certification under 37 CFR. § 3.73, which has not been acknowledged by the Office. Acknowledgement is therefore requested.

It is respectfully submitted that the present application is in condition for allowance. An early notification thereof being earnestly solicited. To the extent necessary, a petition for an

extension of time under 37 C.F.R. 1.136 is hereby made. Please charge any shortage in fees due in connection with the filing of this paper, including extension of time fees, to Deposit Account 500417 and please credit any excess fees to such deposit account.

Respectfully submitted,

McDERMOTT, WILL & EMERY



Cameron Weiffenbach
Registration No. 44,488

600 13th Street, N.W.
Washington, DC 20005-3096
(202) 756-8000 JLT:ajb
Facsimile: (202) 756-8087
Date: February 13, 2004

WDC99 859993-1.050193.0131